Traditional 510(k) Summary

JUN 2 5 2013

A) SUBMITTED BY:

NeuroTherm, Inc.
30 Upton Drive, Suite 2
Wilmington, MA 01887-1083
Registration # 1226344

CONTACT:

F. David Rothkopf
MEDIcept Inc.
200 Homer Ave
Ashland, MA 01721
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B) DEVICE NAME: NeuroTherm Parallax Balloon Inflatable Bone Tamp

COMMON NAME: Arthroscope, Tamp

DEVICE CLASS/: PRODUCT CODE
21 CFR 888.1100 Class II Arthroscope, product code HRX
21 CFR 888.4540 Class I Orthopedic manual surgical instrument, product code HXG (Tamp)
Accessory to 21 CFR 888.3027, Cement/Bone Vertebroplasty, product code NDN

C) PREDICATES:

- Kyphon Xpander II Inflatable Bone Tamp K101864
- KyphX Inflatable Bone Tamp K010246
- KyphX Xpander Inflatable Bone Tamp K041454

D) DEVICE DESCRIPTION:

The NeuroTherm Parallax Balloon Inflatable Bone Tamp is a bone tamp with an inflatable component at the distal end. The tamp is designed to compress cancellous bone and/or move cortical bone as it inflates. The catheter shaft contains an outer lumen for the tamp inflation and a central lumen for a stylet to facilitate catheter introduction. At full inflation volume, the balloon design allows for a uniform balloon that is concentric to the catheter shaft. The wire mandrel provides stiffness to the balloon catheter to facilitate insertion through the access cannula. The NeuroTherm Parallax Balloon Inflatable Bone Tamp may be used with FDA cleared balloon inflation syringes.

E) INTENDED USE/INDICATIONS FOR USE:

The NeuroTherm Parallax Balloon Inflatable Bone Tamp is intended to be used as a conventional bone tamp for the reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation. The Parallax Balloon Inflatable Bone Tamp is to be used with cleared spinal polymethylmethacrylate (PMMA) bone cement indicated for use during percutaneous vertebral augmentation, such as kyphoplasty.

F) SUBSTANTIAL EQUIVALENCE COMPARISON AND DISCUSSION

	NeuroTherm Parallax Balloon Inflatable Bone Tamp	**KyphX Xpander Bone Tamp**	**KyphX Inflatable Bone Tamp**
		K101864/K041454	K010246
Product codes	HRX, HXG Accessory to NDN	HRX, HXG	HRX
Intended Use Indication for Use	The NeuroTherm Parallax Balloon Inflatable Bone Tamp is intended to be used as a conventional bone tamp for the reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation. The Parallax Balloon Inflatable Bone Tamp is to be used with cleared spinal polymethylmethacrylate (PMMA) bone cement indicated for use during percutaneous vertebral augmentation, such as kyphoplasty.	The KYPHON Xpander is intended to be used as a conventional bone tamp for the reduction of fractures and/or creation of a void in cancellous bone in the spine (including use during balloon kyphoplasty with a PMMA-based bone cement that is cleared for use in kyphoplasty procedures) hand, tibia, radius and calcaneus.	KyphX Inflatable Bone Tamps are intended to be used as conventional bone tamps for the reduction of fractures and/or creation of a void in cancellous bone in the spine (including use during balloon kyphoplasty with KyphX HV-R Bone Cement), hand, tibia, radius and calcaneus.
Description			
Tamp	Inflatable bone tamp consisting of a double lumen catheter shaft constructed from two coaxially aligned tubings		
Side adaptor	A side arm adapter provides access to the catheter lumens allowing inflation and deflation		
Straight arm port	A continuous straight arm port in inner catheter lumen allows placement of a non-removable stiffening stylet which attaches to the Luer fitting of the straight arm		
Markers	Radiopaque markers for balloon visualization Exit marker band		
Balloon length indicator	Yes Printed band	Yes Color coded band	
Sterilization	EtO	Gamma irradiation	Unknown

(F) CONCLUSION

The NeuroTherm Parallax Balloon Inflatable Bone Tamp is similar to or the same as the predicate devices for use as follows:

- Technology
- Intended use/Indication for Use in the spine
- Technical specifications or range of technical specifications

Any differences between the NeuroTherm Parallax Balloon Inflatable Bone Tamp and the predicate devices do not raise new issues of safety or effectiveness. Therefore, the NeuroTherm Parallax Balloon Inflatable Bone Tamp is substantially equivalent to the predicate devices.

G) PERFORMANCE TESTING

There are no applicable performance Consensus Standards or Guidance documents associated with this device.

Bench – Bench testing supports that the NeuroTherm Parallax Balloon Inflatable Bone Tamp performs as expected.

H) COMPLIANCE WITH STANDARDS

- ASTM F 565-04 (Reapproved 2009)e1 Standard Practice for Care and Handling of Orthopedic Implants and Instruments (pub date 10/04/2010)
- ANSI/AAMI/ISO 11135:2007 Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical device sterilization for EtO sterilized devices
- ISO 10993-7:2008 Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals
- ISO 594-1 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements
- ISO 594-2 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings
- ISO 10555-1 First edition 1995-06-5 AMENDMENT 2 2004-05-15 Sterile, single-use intravascular catheters - Part 1: General requirements
- ISO 10555-2: 1996 Sterile, single-use intravascular catheters -- Part 2: Angiographic catheters
- ISO 10555-3:1996/ Corrigendum 1:2002 Sterile, single-use intravascular catheters - Part 3: Central venous catheters
- ISO 10555-4: 1996 Sterile, single-use intravascular catheters -- Part 4: Balloon dilatation catheters

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 25, 2013

NeuroTherm, Incorporated
% MEDIcept, Incorporated
Mr. F. David Rothkopf
200 Homer Avenue
Ashland, Massachusetts 01721

Re: K122503
Trade/Device Name: NeuroTherm Parallax Balloon Inflatable Bone Tamp
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: NDN, HRX
Dated: May 13, 2013
Received: May 15, 2013

Dear Mr. Rothkopf:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Erin I. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K122503

Device Name: NeuroTherm Parallax Balloon Inflatable Bone Tamp

Indication for Use:

The NeuroTherm Parallax Balloon Inflatable Bone Tamp is intended to be used as a conventional bone tamp for the reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation. The Parallax Balloon Inflatable Bone Tamp is to be used with cleared spinal polymethylmethacrylate (PMMA) bone cement indicated for use during percutaneous vertebral augmentation, such as kyphoplasty.

Prescription Use X 21CFR 801, Subpart D **OR** Over-the-Counter Use _ 21CFR 801.109

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Laurence D. Coyne -A

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K122503